SUMMARY OF THE REGULATORY COORDINATION COMMITTEE MEETING NOVEMBER 2, 2000

The Regulatory Coordination Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Thursday, November 2, 2000, at 9:00 a.m. Pacific Standard Time (PST) as part of the Sixth NELAC Interim Meeting (NELAC 6i) in Las Vegas, NV. The meeting was led by its chair, Dr. Carl Kircher of the Florida Department of Health. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was discuss items of importance as set forth in the meeting's previously distributed agenda.*

INTRODUCTION

Following a call to order and an introduction of committee members, Dr. Kircher announced that the committee has two vacancies for voting members. He encouraged individuals interested in serving on the committee to indicate their interest on the session's attendance form. Dr. Kircher reviewed the meeting's ground rules and then moved to the first order of business on the agenda.

APPROVAL OF MINUTES OF PREVIOUS MEETINGS

The minutes from the committee's face-to-face meeting at the Sixth NELAC Annual Meeting (NELAC 6) and their October 10 teleconference were approved as written.

DISCUSSION OF DRAFT TO NELAC STANDARD INCORPORATING RE-DEFINITION OF NELAP AND PROFICIENCY TESTING (PT) FIELDS OF TESTING

Dr. Kircher explained that a joint meeting of the NELAC Regulatory Coordination and Program Policy and Structure Committees was held at NELAC 6 to address consistency issues between the National Environmental Laboratory Accreditation Program (NELAP) Scope of Accreditation and the PT Fields of Testing. He noted that participants in an informal straw poll conducted at the joint meeting favored a "matrix-method-analyte" definition for both Scope of Accreditation and PT Fields of Testing. Dr. Kircher reviewed for attendees a handout constituting a summary of proposed language changes to the NELAC Standard and then invited comments from the committee and the floor. Ms. Barbara Burmeister, chair of the NELAC Proficiency Testing Committee, commented that debate at NELAC 6 and in the Proficiency Testing Committee meeting held earlier at NELAC 6i seemed to indicate that there is no need for a one-to-one match between Scope of Accreditation and PT Fields of Testing and that the Proficiency Testing Committee is moving toward a "matrix-analyte" or "matrix-analyte class" definition for PT Fields of Testing. In response, members of the Regulatory Coordination Committee raised the question of whether the NELAC Standard needs to be consistent between chapters. It was noted that one of the criticisms of the NELAC Standard over the last two or three years has been the confusion created for laboratories based on the different terminologies used among the chapters.

A federal regulator noted that removing "method" will cause problems for the U.S. Environmental Protection Agency (EPA) program offices and compliance programs that have mandated methods,

such as drinking water. From the standpoint of federal regulators Fields of Testing terminology needs to be parallel throughout the standard. It was noted that EPA drinking water regulations currently require that laboratories complete one PT sample per year for the method they report for compliance. It was noted that the drinking water program is PT by method and that laboratories are assessed such that they must perform a PT for each method they report, even if the methods are very similar and use the same Standard Operating Procedure (SOP). An audience member noted that his laboratory has a primary method and a back-up method. They handle the PT issue by analyzing one PT in April for inductively coupled plasma (ICP) and another PT in November or October by graphite furnace. The laboratory is then approved for drinking water for both methods and approved by NELAC because they've completed two PTs per year.

There was some discussion of convenient matrix groupings. Dr. Kircher noted that there have been suggestions of the following four manageable matrix groups:

- Drinking Water
- Other Aqueous Liquids/Saline Estuary
- Air
- Biological Tissues/Nonaqueous Liquids/Soils and Sediments/Chemical Waste

Committee members noted that stakeholders have expressed some discontent with grouping biological tissues with other matrices and suggested that it might comprise a fifth matrix group. It was noted that "technology" was not mentioned often in the NELAC Proficiency Testing Committee meeting held on the previous day. This was considered surprising because the inclusion of "technology" was favored in a straw poll conducted in the Program Policy and Structure Committee meeting. In response to a question of whether the Proficiency Testing Committee would consider the inclusion of "technology," Ms. Burmeister answered in the affirmative.

A commenter representing an accrediting authority noted the potential complexity of the PT system and suggested that the process could be made more cost-effective by defining PT Fields of Testing by "matrix-method/technology." and by adopting an 80/20 or 90/10 PT rule. He suggested that such a system would simplify the work of the accrediting authority. It was noted that the manner in which the PT data are used is important to both the accrediting authority and the data user. It was also noted that PT samples are not "real-world" samples and that data end users may not understand the different technologies. A committee member emphasized that the goal of PT is to establish the technical competence of the laboratory and that the data end user only wants to know if the laboratory can analyze its analyte in its matrix at its concentration level of concern. The end user does not really care about technology. The assumption is that the method used will be appropriate to the analyte of interest in the matrix of interest at the concentration level of concern.

There was some discussion of combining matrices into one water matrix instead of separating out drinking water. A commenter noted that this matrix grouping would suffice for PT Fields of Testing but not for Scope of Accreditation because the data end user is being directed by program. It was also noted that one argument against such a matrix grouping is the different concentration levels for the analytes. Water pollution (WP) studies have different levels from Water Supply (WS) studies, for

example. In discussion of what could be done to resolve the issue, two levels of PT samples were suggested, with a PT Fields of Testing definition by "technology level-analyte or analyte class." In such a classification system drinking water, clean water, and Resource Conservation and Recovery Act (RCRA) analytes would be in separate classes. In subsequent discussion it was noted that most of the analyses for these water matrices are alike. One exception is metals analysis. There is no digestion for metals analysis in drinking water, but there is digestion for metals analysis in waste water. It was noted that combining WS/WP analyses would be complicated, in part because the acceptance criteria for drinking water are based on two standard deviations while the acceptance criteria for other water samples are based on three standard deviations. If the two were combined, then one would have to decide the acceptance criteria.

A commenter noted that he has seen situations in which acceptance criteria set by the PT provider are excessively broad. Members of the committee noted that the PT sample relates only to one point in time and that accreditation encompasses much more than the PT. They reiterated that the laboratory's quality system controls the data generated. It was acknowledged that accrediting authorities put much emphasis on PT sample results and that the results are often the basis for suspension of accreditation.

A commenter suggested that stakeholders should push EPA offices and programs to standardize the different methods across all media. In response a federal regulator noted that in a level system there is no reason that the process would not separate into determinative steps and preparatory steps. EPA has struggled for years with the issue of consolidating methods. She noted that there are a number of different frameworks that can be taken. Unfortunately, they are so radically different form the way in which the Agency has evolved that they make it difficult to make fundamental changes in statutory frameworks. She noted that EPA recognizes the difficulties associated with divergent methods just as well as the accrediting authorities and laboratories do. A commenter noted that the PT system is currently doing nothing to test laboratories on preparatory steps. In response a committee member suggested that it is not PT's job to test the preparatory method. It is the job of the on-site assessment.

After considerable discussion, Dr. Kircher summarized the issue. He explained that the Regulatory Coordination Committee has volunteered to facilitate the process by drafting proposed language on various chapters of the NELAC Standard once stakeholders have reached consensus on the issue of Fields of Testing and forwarding the proposed language to the appropriate standing committees. However, it appears that there is still divergence on the issue. Dr. Kircher confirmed with Ms. Burmeister that the Proficiency Testing Committee has opened the issue for discussion but does not yet have a clear direction. The Proficiency Testing Committee is waiting for the Program Policy and Structure Committee to reach a decision. The two committees have been communicating on a regular basis over the past two or three months on this issue. Ms. Burmeister also confirmed that another straw poll would be conducted later in the afternoon. The Regulatory Coordination Committee was in agreement that the Program Policy and Structure, Proficiency Testing, and Accreditation Process Committees would probably be appreciative of some unifying language. The issue is unresolved. Fields of Testing are still being debated. It was decided that the Regulatory Coordination Committee will forward recommended unifying language when the Fields of Testing are decided.

EPA REGULATORY AGENDA

Dr. Kircher explained that it is the committee's charge to notify NELAC meeting participants of regulatory changes that might impact laboratory accreditation. He referred attendees to a handout constituting an executive summary of the EPA regulatory agenda published in April 2000. The agenda includes rules that are complete, rules that have been withdrawn, direct final rules, and proposed rules that EPA intends to promulgate. Direct final rules are rules for which EPA does not anticipate a great deal of controversy. Dr. Kircher explained his organization of the document. The first section of the summary includes proposed test methods. The second section includes industry related effluent regulations, which could indirectly dictate choice of methods that laboratories must use to demonstrate compliance. The document's third section includes air emissions regulations, which could also dictate choice of methods that laboratories must use to demonstrate compliance. Studies for long-term actions of interest to the Agency that could impact laboratories in the future are included in the fourth and final section of the summary document. The unified agenda is available for more detailed study on the Internet at http://ciir.cs.umass.edu/ua. Dr. Kircher noted that anticipated dates for final action are delayed. He noted that Clean Air Act statutory deadlines for promulgation will not be met. Dr. Kircher solicited input from the committee on whether the committee should continue to pay attention to dates or just keep track of items. A committee member suggested that it would be valuable to track dates annually. It was noted that comment periods are not included in the regulatory agenda and that interested parties must check the federal register rule by rule. The regulatory agenda will update rules that are published or promulgated.

DISCUSSION OF MODEL LEGISLATION AVAILABLE

Dr. Kircher referred attendees to a handout constituting model legislation. He noted that several model administrative rules are available on the NELAC Website. The model presented during the meeting consists of a bare bones rule based on the assumption that states can incorporate documents such as the NELAC Standard into the rule by reference. Dr. Kircher noted that the standard approved at NELAC 6 delegated important decision-making authority to the wisdom of the primary accrediting authority. He also noted that states can include their own supplemental regulatory criteria. Dr. Kircher then briefly reviewed the document as follows:

- Certification Criteria - A space for state supplemental criteria regarding additional analytes and methods that are not required under any EPA programs that are part of NELAC has been provided.

- Certification Requirements - This section generally covers the accreditation process. Spaces for state supplemental criteria, such as any statements about laboratory facilities in noncontiguous premises or mobile laboratory facilities requiring separate accreditation, and state Scope of Accreditation, have been provided.

- Certification of Out-of-State Laboratories - There was considerable discussion of this section, which addresses reciprocal agreements. Speaking from his personal experience, Dr. Kircher noted that the state of Florida is obliged to operate their program in a nondiscriminatory manner by making the same requirements in-state and out-of-state laboratories. He noted that NELAP has not had a mechanism for informing all involved parties of which states are accrediting a

laboratory and of when a laboratory is accredited. The national database will provide this information. There was some discussion of how frequently the database will be updated. A commenter referred the committee to Sections 4.1.7.1 and 4.1.7.2 of the Accreditation Process standard for a list of what is required for a secondary accreditation package.

Dr. Kircher explained that the model legislation covers three situations – first-time accreditation, adding a Field of Testing to an existing accreditation, and renewal of accreditation. A federal regulator suggested that there exists a fourth situation of a laboratory under investigation. He raised the question of what happens if a laboratory's documents do not support that primary accreditation is equivalent to the requirements of the secondary accreditation. He suggested that such a situation would constitute giving false statements to a government agency, which is a criminal act. In response Dr. Kircher noted that the accreditation would be denied. Commenters distinguished between the separate processes of offering secondary accreditation to a laboratory that is already accredited by a primary accrediting authority and accrediting a laboratory that is not a NELAP-accredited laboratory. It was noted that some NELAC states have reciprocity with non-NELAC states. There was considerable discussion of the purpose of specified documents for reciprocity between NELAC states.

The committee agreed that portions of Section 2b and Section 2c of this section are redundant and should be removed. Committee members indicated that they also have issues with Sections 3 and 4. These issues were moved to the Parking Lot for discussion at a future teleconference.

C Proficiency Testing (PT) Requirements - Spaces for state supplemental PT requirements, such as a predefined calendar schedule, and state supplemental PT criteria, such as statements about revocation or suspension of certification based on passing or failing PT samples, have been provided. Committee members indicated that they also have issues with portions of this section. These issues were moved to the Parking Lot for discussion at a future teleconference.

C On-site Laboratory Assessments - A space for state supplemental requirements, such as statements about on-site laboratory assessments following a change in laboratory ownership or location or allowances and criteria for adding accreditation without an on-site assessment, has been provided.

C Renewal of Annual Certification - Committee members indicated that they also have issues with portions of this section. These issues were moved to the Parking Lot for discussion at a future teleconference.

C Display of Certificate.

C Contractual Agreements, Records, and Reports - Committee members indicated that they also have issues with portions of this section. These issues were moved to the Parking Lot for discussion at a future teleconference.

C Denial or Revocation of Certification

CONCLUSION

The committee's allotted meeting time having expired, Dr. Kircher thanked participants for their input. He adjourned the meeting shortly after 11:30 a.m. PST.

Attachment A

ACTION ITEMS
REGULATORY COORDINATION COMMITTEE MEETING
November 2, 2000

Item No.	Action	Date to be Completed
1.	Committee will post revised model administrative rules on NELAC Internet site.	01/01
2.	Committee will review October 2000 EPA Regulatory Agenda.	03/01
3.	Committee will present revisions to NELAC Standards based on redefined Fields of Testing to appropriate standing committees	To Be Determined

Attachment B

PARTICIPANTS
REGULATORY COORDINATION COMMITTEE MEETING
NOVEMBER 2, 2000

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